UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,872	01/23/2001	Rina Aharoni	60772-PCT-US/JPW/GJG/CSN	3801

7590 03/26/2002

John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
DECLOUX, AMY M	
ART UNIT	PAPER NUMBER
1644	9

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/768,872	Ahorni et al
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-46 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-46 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Detailed Action

It is noted that a preliminary amendment filed 1-23-01 has not been entered.

1. A restriction is required under 35 USC 121 between one of the following groups:

I. Claims 1-4, 16-20 and 32-39, drawn to a terpolymer consisting essentially of tyrosine, alanine and lysine randomly polymerized into a polypeptide, and a pharmaceutical composition thereof for treating an autoimmune disease, classified in class 530, subclass 350,

II. Claims 5-8, 16, 21-24 and 32-39 drawn to a terpolymer consisting essentially of tyrosine, glutamic acid and lysine randomly polymerized into a polypeptide, and a pharmaceutical composition thereof for treating an autoimmune disease, classified in class 530, subclass 350,

III. Claims 9-12, 16, 25-28 and 32-39, drawn to a terpolymer consisting essentially of glutamic acid, alanine and lysine randomly polymerized into a polypeptide, and a pharmaceutical composition thereof for treating an autoimmune disease, classified in class 530, subclass 350,

IV. Claims 13-16, 29-39 drawn to a terpolymer consisting essentially of tyrosine, alanine and glutamic acid randomly polymerized into a polypeptide, and a pharmaceutical composition thereof for treating an autoimmune disease, classified in class 530, subclass 350,

V. Claims 40-41, drawn to a method of treating an autoimmune disease comprising administering a terpolymer, wherein said terpolymer polypeptide, comprising three different amino acids randomly polymerized into a polypeptide, wherein said three amino acids are tyrosine, alanine and lysine, classified in class 424, subclass 185.1,

VI. Claims 40 and 42, drawn to a method of treating an autoimmune disease comprising administering a terpolymer, wherein said terpolymer polypeptide, comprising three different amino acids randomly polymerized into a polypeptide, wherein said three amino acids are tyrosine, glutamic acid and lysine, classified in class 424, subclass 185.1,

VII. Claims 40 and 43, drawn to a method of treating an autoimmune disease comprising administering a terpolymer, wherein said terpolymer polypeptide, comprising three different amino acids randomly polymerized into a polypeptide, wherein said three amino acids are glutamic acid, alanine and lysine, classified in class 424, subclass 185.1,

VIII. Claims 40 and 44, drawn to a method of treating an autoimmune disease comprising administering a terpolymer, wherein said terpolymer polypeptide, comprising three different amino acids randomly polymerized into a polypeptide, wherein said three amino acids are tyrosine, alanine and glutamic acid, classified in class 424, subclass 185.1,

IX. Claim 45, drawn to a method for treating an autoimmune disease which comprises administering a polypeptide consisting essentially of amino acids tyrosine, glutamic acid, alanine and lysine, wherein the autoimmune disease is not multiple sclerosis, classified in class 424, 185.1,

X. Claim 46, drawn to a kit comprising a water soluble MHC protein, a reaction chamber and a means for detecting binding of the analyte to the MHC protein and a container, classified in class 435, subclass 975,

Note: each claim will be examined only to the extent of the elected invention,
Note: Claim 46 was originally filed as claim 134, but has been renumbered as claim 46 in accordance with Rule 1.126.

The inventions are distinct, each from the other because:

2. Groups V-IX are unique methods, because though each method has the same endpoint, each method comprises administering different ingredients. Therefore, Groups V-IX are patentably distinct.

3. Groups I-IV and Group X are unique products, because each product has a different structure with distinct biophysical properties. Therefore, Groups I-IV and X are patentably distinct.

4. Groups I-IV and Groups V-VIII, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the terpolymer can be used in a method of affinity purification, as well as in the recited method of treating an autoimmune disease.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious

undue burden on the Examiner, restriction for examination purposes as indicated is proper.

6. If Group I-IX is elected, applicant is further required under 35 U.S.C. 121: to elect a product or method comprising a specific autoimmune disease, such as MS as recited in claim 39,

7. Claims 1-16 and 32-46 are generic in at least one aspect.

8. The species are distinct each from the other for the following reasons: Autoimmune diseases differ with respect to their etiology and symptoms.

9. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers **(other than elections)** should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
March 25, 2002
Amy DeCloux 3-25-02